



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/523,681

09/23/2005

Gerald McMorrow

DXUC-1-1043

5818

25315 7590 08/08/2008
BLACK LOWE & GRAHAM, PLLC
701 FIFTH AVENUE
SUITE 4800
SEATTLE, WA 98104

EXAMINER

LAMPRECHT, JOEL

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

08/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,681	Applicant(s) MCMORROW ET AL.	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/06/08 has been entered.

Claim Objections

Claims 2, 7, 11-18, 20-23, 27 and 31-38 are objected to because of the following informalities: Regarding claims 2 and 7 it is unclear what additional structure of the apparatus has been disclosed. Regarding claim 11, "the at least one transducer assembly" conflicts with the limitations of claim 10 from which it depends (see claims 8-11), and "the calibration curve" lacks antecedent basis. Regarding claims 13 and 18 "the transducer assembly" lacks antecedent basis. Regarding claim 14, "the bladder" lacks antecedent basis. Regarding claim 17, it is unclear how a transducer assembly would "display" information. Regarding claim 20, the claim does not set forth that the transducer assembly is used to transmit and receive the signals. Regarding claim 22, it is unclear what additional step in the method is provided as the claim only appears to define structural limitations. Regarding claims 27, 31-38, it is unclear what additional structural limitations have been set forth. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, and 24-43 are rejected under 35 U.S.C. 101 as the claimed invention is directed to non-statutory subject matter. In the instant case, it is set forth that the transducer assembly is positioned in view of the body cavity, attempting to define the structure in terms of the cavity, which appears to be claimed as part of the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subtraction process claimed in claim 6 and 31 was not disclosed within the instant specification. A normalization process was disclosed, but a "word search" within the instant application did not disclose any instance of the term "subtraction" and no discernable use of the term "difference" when applied to subtraction of elements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 is indefinite as it is unclear how a transducer assembly includes a display. In claim 17 it is unclear how a “transducer assembly”, “displays” information.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15, and 17-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al in view of Bradley et al (US 6,905,467 B2). Ganguly disclose all that is listed above, mainly an apparatus capable of measuring the volume of urine in a bladder of an individual through a non-invasive ultrasound technique including a transducer assembly with a plurality of ultrasound transducers (Fig 4), means for activating the ultrasound transducers (Fig 1), means for determining body cavity height and depth (Col 6 Line 5- Col 8 Line 25), as well as filling degree based on known values stored from a patients history (Col 8 Line 35-50). The apparatus also has means for detecting using echo travel time and other beam information, determining which beams intercept the fluid-filled body (Col 4 Line 1 – Col 5 Line 60), display means for display of the calculated fluid volume (Col 8 Line 35-50), means for selecting the number of transducers to indicate bladder filling level (Fig 4, Col 8 Line 15 –50) including a conical beam selection (Col 7 Line 65- Col 8 Line 14), the storage of patient information for the selection of factors for use in volume calculation via a memory (Col 8 Line 35-50), a system provided to adjust the frequency of calculation and display readout (Fig 6, Col 8 Line 35-50), a transducer assembly for locating the walls of the bladder in a single cross-sectional plane (Col 4 Line 35 – Col 5 Line 60), means for showing correct positioning of the transducer assembly (Col 6 Line 30-50), connection to a housing with input device, processor, display, and power supply unit (Fig 6), as well as an ultrasound coupling material covering the transducer for patient convenience (Col 8 Line 25-35). Ganguly et al also disclose mounting the transducer assembly at a predetermined spatial location and angle which can vary over a range(Col 3 Line 15-

30), acoustically coupling the transducers to the skin of the patient (Col 8 Line 25-35), using multiple harmonics or frequency measurements from the transducers to establish boundary lines (Col 4 Line 1 – Col 7 Line 65), and include the entirety of the bladder in the ultrasound measurement, using specific frequencies for the establishment of wall features and alternate frequencies for the measurement of the bladder volume, using specific A-lines for the acquisition of data at selected depths including the front/back walls, and the middle of the human bladder (Col 4 Line 1 – Col 7 Line 65), using both echo data from approximate front and back wall locations to fit and compute a relative location of the outline or edges of the bladder (Col 4 Line 35-45, Col 6 Line 5-50), and finally establishing a volume, comparing that volume to a predetermined threshold value (Col 8 Line 35-50), storing that value for later comparison (Col 8 Line 35-50), and the use of narrow beams within the piezoelectric elements to produce conventional ultrasound signals.

Ganguly et al do not disclose the use of further harmonic components beyond first harmonic frequency within specific calculations, though inherently, harmonic data for additional harmonic frequencies is backscattered and at least received by the receiving means of both of these disclosures and is used to discern what is “fluid-filled” and wall or other outlying area, as propagation times and therefore frequency of signal are accounted for in both the above recited applications. Attention is therefore directed to the teaching reference to Bradley et al which discloses the use of ultrasound harmonic imaging acquisition (Col 1 Line 5- Col 2 Line 40), calibration (Col 11 Line 54 - Col 12 Line 12), attenuation and difference calculation (Col 11 Line 10- Col 12 Line 12).

Art Unit: 3737

It would have been obvious to one of ordinary skill in the art to have applied the statistical analysis, ultrasound acquisition windows, and clinical applications of Ganguly et al with the harmonic acquisition imaging system of Bradley et al for the purpose of acquiring the clearest, most accurate image and volumetric measurement of the bladder volume (Col 4 Line 44-Col 5 Line 22).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ganguly et al in view of Bradley et al (US 6,905,467 B2) as applied to claim 15 above and in further view of Chalana et al (US 7,041,059 B2). Ganguly et al in view of Bradley et al do not disclose providing battery power to the device, attention is then directed to the secondary reference by Chalana which describes a similar diagnostic device using a portable system powered by a battery, and suggests that such a system may be either battery powered or powered conventionally as a matter of choice (Col 4 Line 40 – Col 5 Line 15). Chalana et al describes that a range of frequencies is used, and therefore would have instrumentation to at least acquire reflected signals at harmonic frequencies ($2f = 4 \text{ XHz}$ of 2XHz being $1f$ as an example). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the battery powered elements of Chalana et al with the bladder volume calculation system of Ganguly in view of Bradley to provide a portable element for approximation of the volume of the fluid in the bladder of a patient.

Response to Arguments

Applicant's arguments with respect to claims 1-46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML